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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE SELENIOUS ACID LITIGATION	C.A. No. 2:24-cv-07791 (BRM) (CLW) (Consolidated)

PLAINTIFF'S ANSWER TO DEFENDANT ZYDUS PHARMACEUTICALS (USA) INC.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT

Plaintiff/Counterclaim Defendant American Regent, Inc. ("ARI"), by its undersigned attorneys, hereby responds to the Answer, Separate Defenses, and Counterclaims ("Counterclaims") of Defendant/Counterclaimant Zydus Pharmaceuticals (USA) Inc. ("Zydus") (ECF No. 83) as follows:

GENERAL DENIAL

ARI denies all allegations in Zydus's Counterclaims except for those specifically admitted below. With respect to the allegations made in the Counterclaims, upon knowledge with respect to ARI's own acts, and upon information and belief as to other matters, ARI responds and alleges as follows:

THE PARTIES

1. Zydus is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at 73 Route 31 N., Pennington, New Jersey 08534.

ANSWER: On the basis of Zydus's Answer to Paragraph 3 in its Counterclaims, admitted.

2. Upon information and belief, American Regent is a corporation organized and existing under the laws of the State of New York, with its principal place of business at 5 Ramsey Road, Shirley, New York 11967.

ANSWER: Admitted.

JURISDICTION AND VENUE

3. This Court has jurisdiction over the subject matter of these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202, 35 U.S.C. § 1 et seq., 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5).

ANSWER: Paragraph 3 states legal conclusions for which no response is required. To the extent a response is required, ARI admits that Zydus purports to bring the Counterclaims under the patent laws of the United States and 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202, 35 U.S.C. § 1 et seq., 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5). ARI does not contest subject matter jurisdiction in this judicial district for the purposes of this action only. ARI denies that the Counterclaims have merit or that Zydus is entitled to any relief on its Counterclaims.

4. This Court has personal jurisdiction over American Regent because American Regent commenced and continues to maintain this action against Zydus in this judicial district.

ANSWER: Paragraph 4 states legal conclusions for which no response is required. To the extent a response is required, ARI does not contest personal jurisdiction for purposes of this action only. ARI otherwise denies the allegations of Paragraph 4.

5. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), 21 U.S.C. § 355(j)(5)(C)(i)(II) and because American Regent commenced and continues to maintain this action against Zydus in this judicial district.

ANSWER: Paragraph 5 states legal conclusions for which no response is required. To the extent a response is required, ARI does not contest venue in this judicial district for the purposes of this action only. ARI otherwise denies the allegations of Paragraph 5.

REGULATORY FRAMEWORK

6. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271) (the "Hatch-Waxman Act"), and the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271), a pharmaceutical company seeking approval from the U.S. Food and Drug Administration ("FDA") to sell a new drug must file a New Drug Application ("NDA"), which includes specific data concerning the safety and effectiveness of the drug referenced in the NDA, i.e., the reference-listed drug or RLD.

ANSWER: Paragraph 6 states legal conclusions for which no response is required. To the extent a response is required, admitted.

7. The Hatch-Waxman Act provides that NDA holders shall submit to FDA the patent number and expiration date of any patent that the NDA holder believes "claims the drug for which the applicant submitted the [NDA] . . . and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the [NDA] owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). FDA lists the patent number(s) and expiration date(s) in its publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book").

ANSWER: Paragraph 7 states legal conclusions for which no response is required. To the extent a response is required, admitted.

ORANGE BOOK LISTED PATENT FOR SELENIOUS ACID

8. Upon information and belief, American Regent is the holder of NDA No. 209379 for selenious acid solution, intravenous, 12 mcg/2 mL, 60 mcg/mL, 600 mcg/10 mL.

ANSWER: Admitted.

9. United States Patent No. 12,150,957 ("the '957 patent"), titled "Trace Element Compositions, Methods of Making and Use"— a copy of which American Regent purported to attach to its Complaint as Exhibit A—was issued on November 26, 2024. According to the United States Patent and Trademark Office's ("USPTO") Patent Assignment Search database, Reel/Frame No. 069414/0031, the '957 patent is assigned to American Regent. FDA's Orange Book lists the expiration date of the '957 patent as July 1, 2041.

ANSWER: Admitted.

10. Upon information and belief, the '957 patent is owned by American Regent.

ANSWER: Admitted.

11. Upon information and belief, American Regent submitted the '957 patent to FDA for listing in the Orange Book concerning NDA No. 209379 for selenious acid solution, intravenous, 12 mcg/2 mL, 60 mcg/mL, 600 mcg/10 mL, on December 3, 2024. Accordingly, American Regent maintains and has affirmatively represented that the '957 patent claims the approved drug selenious acid solution or a method of using that drug. Therefore, any ANDA applicant, including Zydus, attempting to sell selenious acid solution before the expiration of the '957 patent has a reasonable apprehension of suit with respect to the '957 patent.

ANSWER: ARI admits that ARI submitted the '957 patent to the FDA for listing in FDA's Orange Book in connection with NDA No. 209379. ARI further admits that ARI sued Zydus for infringement of the '957 patent on December 13, 2024 and that the filed Complaint speaks for itself. *See* ECF No. 1 in C.A. No. 24-11133. The remainder of Paragraph 11 states legal conclusions for which no response is required. To the extent a response is required, denied.

ZYDUS'S ANDA

12. On May 1, 2024, Zydus submitted ANDA No. 219322 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial importation, manufacture, use, or sale of selenious acid solution, intravenous, 12 mcg/2 mL, 60 mcg/mL, 600 mcg/10 mL.

ANSWER: ARI admits that by letters dated June 10, 2024 and June 11, 2024 (the "Zydus Notice Letters"), Zydus notified ARI that Zydus submitted ANDA No. 219322 to market

generic versions of selenious acid solutions, intravenous, 12 mcg/2 mL, 60 mcg/mL, and 600 mcg/10 mL prior to the expiration of the '565 patent.

13. Because Zydus seeks FDA approval to engage in the commercial importation, manufacture, use, or sale of the proposed product described in ANDA No. 219322 before the expiration of the '565 patent, ANDA No. 219322 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") with respect to the '565 patent.

ANSWER: ARI admits that the Zydus Notice Letters notified ARI that Zydus had submitted ANDA No. 219322 to market generic versions of selenious acid solutions, intravenous, 12 mcg/2 mL, 60 mcg/mL, and 600 mcg/10 mL prior to the expiration of the '565 patent. ARI further admits that the Zydus Notice Letters informed ARI that ANDA No. 219322 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") with respect to the '565 patent.

14. Zydus sent a letter dated June 10, 2024, notifying American Regent that Zydus submitted ANDA No. 219322 to FDA seeking approval to engage in the commercial importation, manufacture, use, or sale of Zydus's Proposed ANDA Product and that ANDA No. 219322 includes a Paragraph IV Certification with respect to the '565 patent ("Zydus's Notice Letter").

ANSWER: ARI admits that the Zydus Notice Letters notified ARI that Zydus had submitted ANDA No. 219322 to market generic versions of selenious acid solutions, intravenous, 12 mcg/2 mL, 60 mcg/mL, and 600 mcg/10 mL prior to the expiration of the '565 patent. ARI further admits that the Zydus Notice Letters informed ARI that ANDA No. 219322 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") with respect to the '565 patent.

15. Zydus's Notice Letter includes a statement of the factual and legal bases in support of Zydus's Paragraph IV Certification for the '565 patent.

ANSWER: ARI admits that Zydus sent the Zydus Notice Letters. ARI further admits that the Zydus Notice Letters contained arguments and/or positions that the '565 patent is invalid and/or not infringed, which are not grounded in fact or law and raise material issues to be

resolved in later stages in this proceeding, including claim construction issues and patent infringement and validity issues that will be the subject of fact and expert discovery, neither of which have occurred. ARI denies that Zydus's factual and legal bases have merit. ARI otherwise denies the allegations in Paragraph 15.

COUNT I
(Declaratory Judgment of Noninfringement of U.S. Patent No. 12,150,957)

16. Zydus repeats and realleges the allegations in paragraphs 1-15 above as though fully set forth herein.

ANSWER: No response is required to the general re-allegation and incorporation by reference of the foregoing paragraphs of the Counterclaims. To the extent a response is required, ARI incorporates the answers in response to the foregoing paragraph as if fully set forth herein.

17. By asserting its claim against Zydus for infringement of the '957 patent, American Regent has created a case or controversy regarding the noninfringement of the '957 patent.

ANSWER: Paragraph 17 states a legal conclusion for which no response is required. To the extent a response is required, ARI admits that an actual controversy exists between ARI and Zydus concerning Zydus's infringement of the '957 patent, which is valid and enforceable. ARI denies that Zydus's Counterclaims have merit or that Zydus is entitled to any relief on its Counterclaims. ARI otherwise denies the allegations in Paragraph 17.

18. The commercial importation, manufacture, use, sale, and/or offer to sell within, the United States of the proposed selenious acid solution that is the subject of ANDA No. 219322 would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '957 patent.

ANSWER: Denied.

COUNT II
(Declaratory Judgment of Invalidity of U.S. Patent No. 12,150,957)

19. Zydus repeats and realleges the allegations in paragraphs 1-18 above as though fully set forth herein.

ANSWER: No response is required to the general re-allegation and incorporation by reference of the foregoing paragraphs of the Counterclaims. To the extent a response is required, ARI incorporates the answers in response to the foregoing paragraph as if fully set forth herein.

20. By asserting its claim against Zydus for infringement of the ’957 patent, American Regent has created a case or controversy regarding the validity of the ’957 patent for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting.

ANSWER: Paragraph 20 states a legal conclusion for which no response is required. To the extent a response is required, ARI admits that an actual controversy exists between ARI and Zydus concerning Zydus’s infringement of the ’957 patent. ARI specifically denies that an actual controversy exists between ARI and Zydus concerning invalidity of the ’957 patent. ARI otherwise denies the allegations in Paragraph 20.

21. The claims of the ’957 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

ANSWER: Denied.

PRAYER FOR RELIEF

ARI denies that Zydus is entitled to any judgment or relief against ARI and, therefore, specifically denies Paragraphs (A)–(F) of the Counterclaims’ Prayer for Relief.

Each averment and/or allegation contained in Zydus’s Counterclaims that is not specifically admitted herein is hereby denied.

ARI requests that judgment be entered in its favor, dismissing Zydus’s Counterclaims with prejudice, awarding ARI’s attorneys’ fees and costs incurred in this litigation under 35 U.S.C. § 285, and granting even further relief as the Court may deem just and proper.

Dated: January 28, 2025

By: s/ Charles H. Chevalier

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CERTIFICATE OF SERVICE

I hereby certify that on January 28, 2025, a true and correct copy of Plaintiff's Answer to Defendant Zydus Pharmaceuticals (USA) Inc.'s Answer, Affirmative Defenses, and Counterclaims to Plaintiff's Complaint was served by ECF on all counsel of record and electronic mail on all counsel of record for Zydus.

Date: January 28, 2025

s/ Charles H. Chevalier

Charles H. Chevalier